5. 510(k) Summary

K083889

Submitter's Name: Fotona d.d.
Stegne 7
SI-1210 Ljubljana, Slovenia
Phone: +386 15009100
Fax: + 386 5009 200

Contact Person: Stojan Trošt, QA&RA Manager
Phone: + 386 1 5009 299
E-mail: stojan.trost@fotona.com

APR 23 2009

Date: December 22, 2008

Device Name:
Trade name: Fotona QX Nd:YAG/KTP Laser System Family
Common name: Nd:YAG/KTP Dermatology and Surgical Laser
Classification name: Instruments, Surgical, Powered, Laser
79-GEX

DEVICE DESCRIPTION

The Fotona QX laser system family is based on the Nd:YAG (1064 nm) and frequency doubled KTP Nd:YAG (532 nm) laser technology. There is one optical cavity containing the Nd:YAG crystal. The frequency doubled KTP Nd:YAG wavelength is achieved by directing the Nd:YAG laser beam through a frequency doubling non-linear crystal. The Nd:YAG laser is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided by articulated arm to a focusing variable spot handpiece. Optionally, the KTP Nd:YAG beam can be guided to a 585nm dye converter handpiece, or to a 650nm dye laser converter handpiece. The dye handpieces convert the KTP 532 nm wavelength beam into a 585 nm or a 650 nm wavelength, correspondingly. Both lasers are used in non-contact mode. The user activates laser emission by means of a footswitch.

The Nd:YAG (1064 nm) laser can be operated in a Q-switched (nominal pulse duration 5-20 nsec) and in a non-Qswitched mode (nominal pulse duration 0.25 msec) of operation. The KTP:YAG (532 nm) laser with optional 585 nm and 650 nm wavelengths can be operated only in a Q-switched mode (nominal pulse duration 5-20 nsec).

In the Q-switched mode, the Nd:YAG (1064 nm) laser is capable of delivering up to 1.6 J of laser energy. Spot sizes available range from 2 to 8 mm.

In the non-Q-switched mode, the Nd:YAG (1064 nm) laser is capable of delivering up to 5 J of laser energy. Spot sizes range from 2 to 8 mm.

The frequency doubled Nd:YAG (532 nm) KTP laser delivers up to 0.6 J of laser energy in 5-20 nanosecond pulses. Spot sizes available range from 2 to 8 mm.

All three modes of operation are intended to be used for incision/excision, ablation, vaporization of soft tissue in general dermatology and for the indications for use as stated below.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Fotona believes that its Fotona QX Nd:YAG/KTP laser system family is substantially equivalent to other legally-marketed predicate devices. The Fotona QX Nd:YAG/KTP laser system family is comparable to the following predicate devices in terms of its indications for use, technical specifications, operating performance features, and general design features:

a) Fotona QX Nd:YAG/KTP Laser System (K053139) previously cleared for :
Incision, excision, ablation, vaporization of soft tissue for general dermatology.

Q-switched Nd:YAG 1064 nm wavelength:
- removal of dark ink (black, blue and brown) tattoos
- removal or lightening of unwanted hair
- treatment of common nevi
- skin resurfacing with or without adjuvant preparation

Q-switched KTP Nd:YAG 532 nm wavelength:
- removal of light ink (red, tan, purple, and orange) tatoos
- removal of pigmented lesions, removal of vascular lesions
- treatment of lentigines, treatment of cafe-au-lait birthmarks
- treatment of common nevi
- treatment of seborrheic keratosis
- treatment of post inflammatory hyperpigmentation

b) Hoya RevLite Q-Switched Nd:YAG Laser System (K063834) previously cleared for:
Incision, excision, ablation, vaporization of soft tissue for general dermatology.

Q-switched 1064 nm wavelength:
- tatoo removal : dark ink (black & blue)
- treatment of nevus of Ota
- removal or lightening of unwanted hair with or without adjuvant preparation
- skin resurfacing procedures for the treatement of acne scars and wrinkles

Q-switched 532 nm wavelength (nominal delivered energy of 585 nm and 650 nm with the optional dye laser handpieces):
- Removal of light ink (red, sky blue, green) tatoos
- Treatment of vascular lesions including, but not limited to:
  - port wine birthmarks
  - telangiectasias
  - spider angioma
  - cherry angioma
  - spider nevi
- Treatment of pigmented lesions including, but not limited to:
  - cafe-au-lait birthmarks
  - solar lentiginos
  - senile lentiginos
  - Becker's nevi
  - freckles
  - nevus spilus
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

c) Candela GentleYAG Family of Laser Systems (K033172) previously cleared for:

Non-Q-Switched 1064 nm Nd:YAG wavelength:
- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin

- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles

d) Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K070355) previously cleared for:

Non-Q-Switched 1064 nm Nd:YAG wavelength:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telengiectasiae, rosacea, venus lake, leg veins and spider veins
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

e) Cooltouch Nd:YAG Laser System (K040131) previously cleared for:

- Treatment of mild to moderate inflammatory acne vulgaris

f) Palomar StarLux Pulsed Light System (K041086) previously cleared for:

- Treatment of mild to moderate inflammatory acne vulgaris

Details are provided in the Substantial Equivalence Discussion Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

Fontana D.D.
% Mr. Stojan Trost
Quality Assurance and Regulations Affairs Manager
Stegne 7
SI- 1210 Ljublijana
Slovenia

Re: K083889
Trade/Device Name: Fotona QX Nd: YAG/KTP Laser System Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Dated: April 3, 2009
Received: April 6, 2009

Dear Mr. Trost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K083889

Device Name: Fotona QX Nd:YAG/KTP Laser System Family

Indications for Use:

The Fotona QX Nd:YAG/KTP Laser System Family is indicated for incision, excision, ablation and vaporization of soft tissue for general dermatology.

Specific Indications:

1064 nm wavelength in Q-switched mode:

- Removal of dark ink (black, blue and brown) tattoos
- Treatment of nevus of Ota
- Treatment of common nevi
- Removal or lightening of unwanted hair
- Skin resurfacing procedures for the treatement of acne scars and wrinkles

1064 nm wavelength in non- Q-switched mode:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces):

- Removal of light ink (red, sky blue, green, tan, purple, and orange) tatoos
- Treatment of vascular lesions including, but not limited to:
  - port wine birthmarks
  - telangiectasias
  - spider angioma
  - cherry angioma
  - spider nevi

for mxn

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- Treatment of pigmented lesions including, but not limited to:
  - cafe-au-lait birthmarks
  - solar lentigines
  - senile lentigines
  - Becker's nevi
  - freckles
  - common nevi
  - nevus spilus
- Treatment of seborrheic keratosis
- Treatment of post inflammatory hyperpigmentation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

Prescription Use: __X___ AND/OR Over-The-Counter Use:_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

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